



## INTEGRATED BIOREPOSITORY OF H3AFRICA UGANDA

### MAKERERE UNIVERSITY COLLEGE OF HEALTH SCIENCES

#### STANDARD OPERATING PROCEDURE

TITLE: **IDENTIFICATION, LABELLING AND TRACKING**

PAGE 1 of 6

SOP #: **IBRH<sub>3</sub>AU-SOP-BSP-003.1**

Effective Date: **09/01/2014**

Next Rev: **DEC 2015**

Prepared by :

Reviewed by:

Approved by:

(Signature & Date)

NAME: Musinguzi Henry  
TITLE: Lab Manager

(Signature & Date)

NAME: Dr. Samuel Kyobe  
TITLE: Coordinator

(Signature & Date)

NAME: Prof. Moses Joloba  
TITLE: Principal Investigator

#### VALIDATION AND RETIREMENT

	NAME	DATE
Validated by:		
Retired by:		

#### ACKNOWLEDGEMENT OF READING AND UNDERSTANDING

**I have received and understood the training on this SOP. If I have not understood the training I have asked the trainer to retrain me to ensure that I completely understand all the requirements.**

	NAME	SIGNATURE	DATE
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			



## INTEGRATED BIOREPOSITORY OF H3AFRICA UGANDA

### STANDARD OPERATING PROCEDURE

TITLE: <b>IDENTIFICATION, LABELLING AND TRACKING</b>		Supersedes SOP#: None
SOP#: <b>IBRH<sub>3</sub>AU-SOP-BSP-003.1</b>	Effective Date: <b>09/01/2014</b>	Next Rev: <b>DEC 2015</b>

## Table of Contents

<b>VALIDATION AND RETIREMENT.....</b>	<b>1</b>
<b>ACKNOWLEDGEMENT OF READING AND UNDERSTANDING .....</b>	<b>1</b>
<b>1. INTRODUCTION.....</b>	<b>3</b>
<b>2. PURPOSE .....</b>	<b>3</b>
<b>3. SCOPE.....</b>	<b>3</b>
<b>4. RESPONSIBILITIES .....</b>	<b>3</b>
<b>5. MATERIALS, REAGENTS, EQUIPMENTS AND FORMS.....</b>	<b>4</b>
<b>6. PROCEDURE.....</b>	<b>4</b>
<b>7. REFERENCES, REGULATIONS AND GUIDELINES.....</b>	<b>5</b>
<b>8. REVISION HISTORY .....</b>	<b>6</b>



## INTEGRATED BIOREPOSITORY OF H3AFRICA UGANDA

### STANDARD OPERATING PROCEDURE

TITLE: <b>IDENTIFICATION, LABELLING AND TRACKING</b>		Supersedes SOP#: None
SOP#: <b>IBRH<sub>3</sub>AU-SOP-BSP-003.1</b>	Effective Date: <b>09/01/2014</b>	Next Rev: <b>DEC 2015</b>

#### 1. INTRODUCTION

This procedure is intended to ensure that biospecimen obtained from consented participants are appropriately identified and tracked to eliminate the risks of sample misidentification and loss.

#### 2. PURPOSE

The purpose is to outline general procedures that can be used when collecting biospecimen to ensure that labeling and tracking are maintained with essential standards to prevent loss of biospecimen due to inadequate identifying information.

#### 3. SCOPE

This SOP describes how biospecimen are labeled and tracked.

#### 4. RESPONSIBILITIES

This SOP applies to all personnel that are responsible for obtaining, processing, storing and tracking biospecimens in BRH3AU operations. Applicable staff may include the following roles.

Personnel	Responsibility/Role
Consent Nurse	Obtain Patient Consent
Phlebotomist/Venipuncture nurse	Collect blood from patient and label specimen
Laboratory Staff	Processes and stores biospecimens.
QC manager	Responsible for Operation and Quality Assurance at the biorepository



## INTEGRATED BIOREPOSITORY OF H3AFRICA UGANDA

### STANDARD OPERATING PROCEDURE

TITLE: <b>IDENTIFICATION, LABELLING AND TRACKING</b>		Supersedes SOP#: None
SOP#: <b>IBRH<sub>3</sub>AU-SOP-BSP-003.1</b>	Effective Date: <b>09/01/2014</b>	Next Rev: <b>DEC 2015</b>

## 5. MATERIALS, REAGENTS, EQUIPMENTS AND FORMS

- 5.1 Appropriate labels such as cryogenic and Thermal transfer tags.
- 5.2 Computerized inventory system.
- 5.3 Label printer.
- 5.4 Label scanner/barcode reader.

## 6. PROCEDURE

### 6.1 Labeling of Biospecimen

- 6.1.1 Label all human biological biospecimen taken from recruited participants.
- 6.1.2 Make sure that each label used adheres tightly to the receptacle/tube.
- 6.1.3 Only include information on the label that is compliant with the project protocol, which adheres to applicable privacy legislation.
- 6.1.4 If there is sufficient space on the label, additional information may be included. Only include static information (i.e. information that will not change for that sample).
- 6.1.5 All labeling should be facilitated by computer entry. This will eliminate problems that arise due to variations in handwriting and misreading of labels.
- 6.1.6 Always use the bar coded labeling system, unless it is not available.

### 6.2 Tracking and Inventory System

- 6.2.1 Assign a unique identifier such as a tracking number or bar code to each sample at the time of collection. This same identifier will be associated to all clinical and scientific data for the sample.
- 6.2.2 Update the inventory or tracking system to create an alert if there is any movement or change in the sample or data within or outside the biorepository.
- 6.2.3 Only participate in the tasks that you are specifically assigned to do (e.g., entering data).
- 6.2.4 Generate a unique identifier (address) for each freezer, refrigerator, or storage cabinet. Identify specific shelves, racks, boxes that will be specific for biorepository biospecimen.
- 6.2.5 Once biospecimen are entered into the inventory system, the system will be used to track sample type, date of collection, volume of sample, sample movement, shipment and thaws and deviations from regular storage conditions if necessary.



## INTEGRATED BIOREPOSITORY OF H3AFRICA UGANDA

### STANDARD OPERATING PROCEDURE

TITLE: <b>IDENTIFICATION, LABELLING AND TRACKING</b>		Supersedes SOP#: None
SOP#: <b>IBRH<sub>3</sub>AU-SOP-BSP-003.1</b>	Effective Date: <b>09/01/2014</b>	Next Rev: <b>DEC 2015</b>

## 7. REFERENCES, REGULATIONS AND GUIDELINES

- 7.1 Declaration of Helsinki  
<http://www.wma.net/en/30publications/10policies/b3/index.html>
- 7.2 Human Tissue and Biological Biospecimen for use in Research. Operational and Ethical Guidelines. Medical Research Council Ethics  
<http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002420>
- 7.3 Best Practices for Repositories I. Collection, Storage and Retrieval of Human Biological Materials for Research. International Society for Biological and Environmental Repositories (ISBER).  
[http://www.isber.org/Search/search.asp?zoom\\_query=best+practices+for+repositories](http://www.isber.org/Search/search.asp?zoom_query=best+practices+for+repositories)
- 7.4 National Bioethics Advisory Commission: Research involving human biological materials: Ethical issues and policy guidance, Vol. I: Report and recommendations of the National Bioethics Advisory Committee. August 1999



## INTEGRATED BIOREPOSITORY OF H3AFRICA UGANDA

### STANDARD OPERATING PROCEDURE

TITLE: <b>IDENTIFICATION, LABELLING AND TRACKING</b>		Supersedes SOP#: None
SOP#: <b>IBRH<sub>3</sub>AU-SOP-BSP-003.1</b>	Effective Date: <b>09/01/2014</b>	Next Rev: <b>DEC 2015</b>

### 8. REVISION HISTORY

Revision No	Effective Date	Description of Changes Made from Preceding Revision	Approved by/ Date

### ANNEX 1: DOCUMENTATION OF SUGGESTED CHANGES TO THIS SOP

CLAUSE	SUGGESTION	BY	DATE